



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0660; FRL-9156-01-OCSPP-01]

Agency Information Collection Activities; Proposed Renewal and Consolidation of Two Currently Approved Collections under Section 5 of the Toxics Substances Control Act; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit a request to renew and consolidate two existing approved Information Collection Requests (ICRs) to the Office of Management and Budget (OMB). Before submitting the consolidated ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The consolidated ICR is entitled: “TSCA Section 5 Reporting and Recordkeeping for Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances” and identified by EPA ICR No. 2702.01 and OMB Control No. 2070-NEW. EPA is consolidating these two existing approved ICRs because the information required to be collected and maintained is similar for both collection activities. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0660, using the *Federal eRulemaking Portal* at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) is open to the public by appointment only. For the latest status information on EPA/DC and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Mission Support Division, (7101M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1204; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A), 44 U.S.C. 3506(c)(2)(A), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Should I Consider when I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible, include specific examples and describe any assumptions that you used.
- Provide copies of any technical information and/or data you used that support your views.
- If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
- Submit your comments by the deadline identified under **DATES**, and be sure to identify the docket ID number assigned to the ICR in the subject line on the first page of your response. You may also provide the ICR title and related EPA and OMB numbers.

III. What Do I Need to Know About PRA?

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to PRA approval unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instruments or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

As used in the PRA context, burden is defined in 5 CFR 1320.3(b).

IV. What Information Collection Activity or ICR Does this Action Apply to?

Title: TSCA Section 5 Reporting and Recordkeeping for Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances.

ICR number: EPA ICR No. 2702.01

OMB control number: OMB Control No. 2070-NEW.

ICR status: This is a new ICR that reflects the consolidation of the following two currently approved ICRs:

1. “TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals” (identified by EPA ICR No. 1188.12 and OMB Control No. 2070-0038), which is currently approved through July 31, 2022; and

2. “Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances” (identified by EPA ICR No.0574.18 and OMB Control No. 2070-0012), which is currently approved through December 31, 2022.

Abstract: The information collection activities in the consolidated ICR addresses the reporting and recordkeeping requirements associated with the new chemical substances review and regulatory program and the existing chemicals program administered by EPA under section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the “Lautenberg Act”) (15 U.S.C. 2604).

TSCA section 5 requires that any person who proposes to manufacture (which includes import) a “new chemical” (i.e., a chemical not listed on the TSCA section 8(b) Inventory) must provide a premanufacture notice (PMN) or an exemption application to EPA at least 90 days prior to commencing manufacture of that chemical and that EPA review such notice and take action as appropriate. EPA considers certain genetically engineered microorganisms to be chemical substances for purposes of the notification requirements found in TSCA section 5; the 90-day notice for microorganisms is a Microbial Commercial Activity Notice (MCAN).

Under TSCA section 5, EPA is authorized to determine that a non-ongoing use of a new or existing chemical substance is a significant new use and promulgate a significant new use rule (SNUR). When someone opts to pursue the manufacture (import) or processing of the chemical substance for that use, they must first submit a significant new use notice (SNUN) to EPA from any person who proposes to manufacture or process a chemical for a use that is determined

by EPA to be a “significant new use.” Note that the scope of this ICR only includes reporting of estimates for respondent activities associated with SNURs in instances where a SNUN is submitted. For more information on new and existing chemical SNURs, see a recent EPA Economic Analysis for new chemical SNURs issued under 40 CFR 721 Subpart D - Expedited Process, and the Supporting Statement for “TSCA section 5(a)(2) Significant New Use Rules for Existing Chemicals Information Collection Request.”

TSCA section 5 requires EPA to make determinations before the conclusion of its review of the submitted notices regarding whether the manufacture, processing, distribution in commerce, use and/or disposal of the new chemical substances or the significant new use of the existing chemical substances may present unreasonable risk to health or the environment. EPA’s determination on a chemical substance or new use will dictate how and to what extent the chemical’s manufacture, use, processing and/or disposal may be restricted. If EPA fails to make a timely determination, fees may be refunded; however, nothing relieves EPA of its obligation to make a determination. EPA requires that the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question actually begins by submitting a Notice of Commencement; EPA would then add the new chemical substance to the TSCA section 8(b) Inventory.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and regulations that interpret TSCA section 12(b) appear at 40 CFR part 707 and the associated paperwork activities and burdens are approved under OMB Control No. 2070-0030, ICR entitled “Notification of Chemical Exports - TSCA Section 12(b),” identified by EPA ICR No. 0795.16.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to be between 17 to 526 hours per response. The consolidated ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

Respondents/Affected entities: Entities potentially affected by this ICR are chemical manufacturers (defined by statute to include importers) and processors, e.g., entities identified by the North American Industrial Classification System (NAICS) codes 325, Chemicals and Allied Products Manufacturers, and 324, Petroleum Refining.

Estimated total number of potential respondents: 234.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 5.74.

Estimated total annual burden hours: 136,292 hours.

Estimated total annual costs: \$ 37,354,814. This includes an estimated burden cost of \$ 37,354,814 and an estimated cost of \$ 0 for non-burden hour paperwork costs, e.g., capital investment or maintenance and operational costs.

V. Are There Changes in the Estimates from the Last Approvals?

The consolidation of the currently approved ICRs is expected to result in an overall decrease of 55,863 burden hours and \$ 17,188,154 burden costs when compared to the total combined burden and costs that is currently approved by OMB. This decrease in the total estimated burden and costs is primarily due to the declining number of TSCA section 5 submissions for new chemicals, and other adjustments made in EPA's estimates of the number of respondents, as well as the related burden and costs estimates. This change is an adjustment.

In addition, OMB has requested that EPA move towards using the 18-question format for ICR Supporting Statements used by other federal agencies and departments and that is based on the submission instructions established by OMB in 1995, replacing the alternate format developed by EPA and OMB prior to 1995. The Agency does not expect this change in format to result in substantive changes to the information collection activities or related estimated burden and costs.

VI. What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the consolidated ICR as

appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity for the public to submit additional comments for OMB consideration. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: December 21, 2021.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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